GE Healthcare

Kvick Lab and Kvick Flow Cassettes User Manual

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Table of contents

Introduction

About this user manual 3
Audience 3
Where to find more information 3
Safety 3

Section 1—Cassettes

Package contents 4
Cassette structure 4
Product labeling 4

Section 2—Using a cassette

Introduction 5
Cassette preparation 5
Operating conditions 5
Product recovery 5
Cassette cleaning 6
Storing a cassette 6
Chemical compatibility 6

Section 3—Product information

Ordering information 7
- Kvick Lab cassettes 7
- Kvick Flow cassettes 7

Introduction

About this user manual

This user manual describes how to use Kvick™ Lab and Kvick Flow membrane cassettes. Topics include preparation, operating conditions, cleaning and storing, and product information.

Audience

This user manual addresses personnel who have experience in cross flow filtration and who have the proper documentation, knowledge, and skills to safely operate cross flow equipment that is used with Kvick Lab and Kvick Flow cassettes.

Where to find more information

For further information please contact us in the US at:

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or, visit our Web site at:
www.gehealthcare.com

For additional contact information at our offices around the world, refer to the listings on the back cover of this manual.

Please visit our Web site at www.gehealthcare.com, where you can learn about all of GE Healthcare chromatography and membrane products for biopharmaceutical processing. The latest edition of this manual as well as other technical literature is available for download through links provided at this site.

Safety

Kvick Lab and Kvick Flow cassettes are designed for use with Kvick Lab and Kvick Flow cassette holders under the specified process conditions stated in this and other GE Healthcare documentation.

Only trained personnel who understand the operating instructions should install and operate Kvick Lab and Kvick Flow cassettes. Users should follow the safety regulations established by the US Occupational, Safety and Health Administration (OSHA); other applicable federal, state, and local regulations; company policy; and the specific safety instructions provided in product documentation.

Overpressurizing a cross flow filtration system may rupture system components and cause bodily harm. Install pressure gauges and regulator to limit the feed pressure to 4 barg (60 psig) when testing and operating the system.

System leakage may release hazardous fluids and cause bodily harm. To minimize this risk, periodically inspect the gaskets, seals, and connections for wear, depressurize the system before disassembling, and wear appropriate personal protective equipment when operating the system.

Mishandling potentially hazardous process or cleaning solutions can cause bodily harm. Read the material safety data sheets for process solutions and follow the safety instructions.

The cassette storage solution contains 0.1 to 0.2 N NaOH and glycerin. Follow the standard safety procedures for handling aqueous NaOH described in this user manual and wear appropriate personal protective equipment.

To avoid damaging the cassette, do not drop, use excessive feed pressure, pressurize the permeate ports, expose to incompatible chemicals, run at greater than 50°C or 4 barg (60 psig), dry the membrane, or subject to freezing.

Section 1

Cassettes

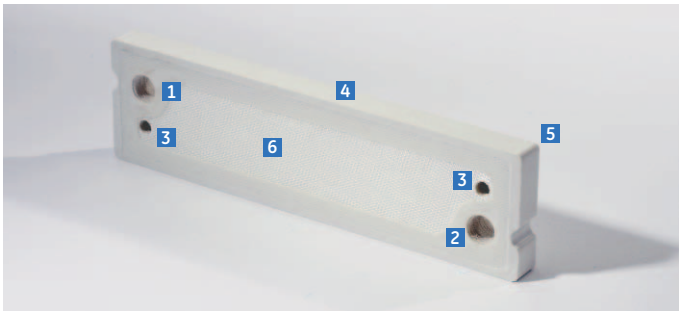
Package contents

Cassette boxes include the following components:

- Cassette in sealed plastic bag
- Cassette gasket
- Certificate of compliance
- Retrofit guide
- User manual

Cassette structure

The two sizes of Kvick Lab and Kvick Flow cassettes share design components, including inlet and outlet ports, labeling, and alignment notches (Fig 1).



1. Inlet (feed) port
2. Outlet (retentate) port
3. Permeate port
4. Cassette information
5. Alignment notches
6. Incorporated gasket

Figure 1. The main parts of a GE Healthcare cassette

Product labeling

The cassette label is laser-engraved on the side of the cassette. It contains manufacturer, lot number, cassette type (Kvick Lab or Kvick Flow), part number, nominal molecular weight cutoff (NMWC), and membrane area in square meters and square feet (Fig 2).

Figure 2. Sample product label

Section 2

Using a cassette

Introduction

This section provides basic procedures for cassette preparation, operation, cleaning, and storage. This section does not cover process optimization.

Cassette preparation

Before using a new or used-and-stored cassette, rinse the storage solution from the cassette following these steps:

1. Open the cassette bag, drain the cassette, and rinse the storage solution from the exterior of the cassette with high purity water. Use appropriate personal protective equipment to avoid contact with the NaOH/glycerin storage solution.
2. Configure a filtration system according to Figure 3. Install the cassette in the cassette holder. (See the Cassette Holder User Manual for specific installation instructions.) Close the feed, retentate, and permeate valves.
3. Direct the retentate and permeate lines to waste.
4. Fill the reservoir with deionized (DI) water or water for injection (WFI) (5 liters per 0.09 m^2 [1.0 ft^2] of membrane area).
5. Open the feed and retentate valves. Close the permeate valve. Pump about 10% of the water through the retentate line to waste at a feed pressure of 0.3 barg (5 psig).
6. Open the permeate valve and close the retentate valve. Pump the remaining water through the permeate line to waste at a transmembrane pressure (TMP) of 0.3 barg (5 psig).
7. Optionally, analyze a permeate sample to verify sufficient flushing for your specific application. Flush with additional water, if needed.
8. Drain the water. Add a sufficient volume of buffer to the feed tank to maintain an adequate working volume. Circulate buffer through the filtration system for up to five minutes to condition it prior to addition of process fluid. Drain the buffer.

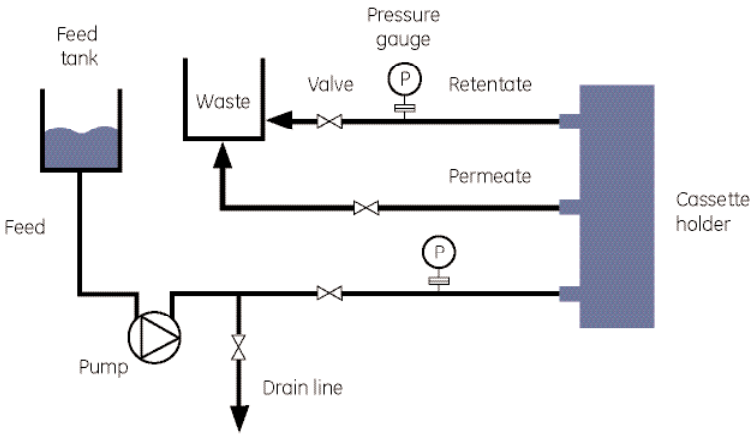


Figure 3. Typical setup for rinsing cassettes

Operating conditions

When using Kvick cassettes, process optimization is highly recommended. Typically, an effective cross flow rate will range from 5.4 to 8.6 liters per m^2 (600-800 ml per ft^2) of membrane, and the permeate pressure will be zero. The maximum feed pressure for Kvick cassettes is 4 barg (60 psig) at 50°C.

Before beginning a filtration, it may be useful to generate a pump curve that relates pump speed to flow rate. This curve allows easy adjustment of filtration flow rate, eliminating the need to physically measure the flow rate and adjust through trial and error. Alternatively, a flowmeter may be used.

Product recovery

The yield of product in the retentate is generally increased by using a product recirculation after filtration.

1. Close the permeate valve.
2. Reduce the cross flow to 10% of the process cross flow.
3. Recirculate the fluid for 5-15 minutes.

To recover product from the feed tank, use the drain valve that, depending on system configuration, may be before or after the pump. To evacuate product from the remainder of the system, specific system design will dictate whether to operate the pump slowly in either the forward or reverse direction or to drain the system by gravity.

Cassette cleaning

Cassettes should be cleaned properly before reuse or storage. Before cleaning, cassettes should be rinsed with buffer and water. It is highly recommended to optimize the cassette cleaning methods. The following is a general cassette cleaning protocol:

1. Direct the retentate and permeate lines to the feed tank (Fig 4). Open the feed and retentate valves. Close the permeate valve.
2. Circulate a minimal volume of buffer across the retentate side for 5-10 minutes at 1-1.5× the process cross flow.
3. Drain the system. Add a minimal volume of water and circulate water across the retentate side for 5-10 minutes at 1-1.5× the process cross flow.
4. Drain the system. Add cleaning solution to the feed tank at a ratio of 15-20 liters per m^2 (1.5-2 liters per ft^2) of membrane area. See Table 1 for typical cleaning conditions.
5. Open the feed and retentate valves and pump about 10% of the cleaning solution through the retentate line to waste.
6. Open the permeate valve, close the retentate valve, and pump about 10% of the cleaning solution through permeate line to waste.
7. Stop the pump and direct the retentate and permeate lines into the feed tank. Open the feed, retentate, and permeate valves.
8. Start the pump and adjust the cross flow to 1-1.5× the process cross flow. Circulate the cleaning solution for 30-60 minutes.
9. Drain the cleaning solution from the system.
10. Flush the system using 15-20 liters of clean water per m^2 (1.5-2 liters per 1.0 ft^2) of membrane area and the same process described in steps 5 through 9 above. The circulation time may be reduced to 15 minutes.

Cleaning efficacy is commonly evaluated by comparing clean water fluxes pre- and post-use. It is good practice to record clean water flux after each cleaning. Commonly, users will discard cassettes if the water flux has reduced to 60-70% of original water flux. Note that reduced water flux often does not indicate that process fluid flux will likewise be reduced.

Table 1. Recommended cleaning conditions

Cleaning agent	Cleaning conditions
0.1-0.5 N sodium hydroxide	Contact time = 60 minutes Temperature = 40°C (113°F)
0.5 N NaOH with 100-300 ppm sodium hypochlorite	Contact time = 60 minutes Temperature = 20°C (68°F)

Storing a cassette

Cleaned cassettes should be stored according to the conditions outlined in Table 2. These conditions keep the membrane wetted and inhibit microbiological growth. Introduce the storage solution into the cassette as per the instructions for cleaning, steps 4 through 8. The recirculation time (step 8) may be reduced to 10-15 minutes.

It is good practice to store cassettes under refrigeration, and this is especially recommended for long-term storage (i.e., 1-12 months). Store cassettes in air-tight containers and add a small volume of storage solution to the containers to minimize evaporation. Alternatively, cassettes may be submerged in storage solution for up to one month. For short-term storage (up to 3 days), cassettes may be stored in holders that are compressed through a torquing mechanism. In this case, disconnect the electrical power to the feed pump, and ensure that the feed tank is properly sealed. Preferably, the tie rod nuts should be loosened and retightened to a torque of 10-15 Nm (88-133 in-lbs). This step must only be done when the system is depressurized and the holder does not contain fluid. It is not recommended to store cassettes in holders that are compressed through a hydraulic sealing mechanism.

Table 2. Recommended storage conditions

Duration	Temperature	Chemical
Up to 3 days	Ambient (20-25°C)	Water or 1-3% NaOCl
Up to 1 month	Ambient (20-25°C)	0.1 N NaOH
Up to 12 months	Refrigerated (4°C)	0.05 N NaOH

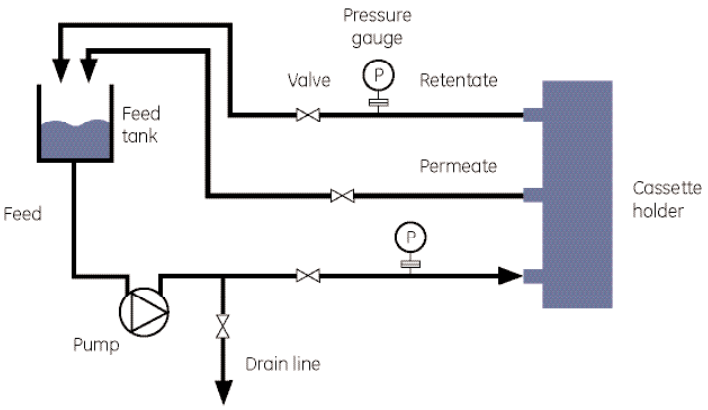


Figure 4. Typical setup for recirculation of cleaning solution

Chemical compatibility

Kvick Lab and Kvick Flow cassettes are resistant to most chemicals typically used in bioprocessing. Because chemical compatibility is dependent on the chemical as well as the exposure time and temperature, specific compatibility questions should be answered experimentally.

Section 3

Product information

Ordering information

Table 3. Kvick Lab cassettes

Code number	Catalog number	Membrane area (m^2)	Membrane area (ft^2)	Rating (NMWC*)	Holdup volume (ml)
56-4112-02	UFELA 0005 001 ST	0.01	0.1	5 kD	2
56-4112-06	UFELA 0010 001 SE	0.01	0.1	10 kD Select**	2
56-4112-04	UFELA 0010 001 ST	0.01	0.1	10 kD	2
56-4112-08	UFELA 0030 001 ST	0.01	0.1	30 kD	2
56-4112-10	UFELA 0050 001 ST	0.01	0.1	50 kD	2
56-4112-14	UFELA 0100 001 ST	0.01	0.1	100 kD	2
56-4113-31	UFELA 0005 001 ST	0.11	1.2	5 kD	20
56-4113-26	UFELA 0010 010 SE	0.11	1.2	10 kD Select**	20
56-4113-25	UFELA 0010 010 ST	0.11	1.2	10 kD	20
56-4113-27	UFELA 0030 010 ST	0.11	1.2	30 kD	20
56-4113-28	UFELA 0050 010 ST	0.11	1.2	50 kD	20
56-4113-29	UFELA 0100 010 ST	0.11	1.2	100 kD	20

* Nominal molecular weight cutoff
** 10 kD Select is a tighter 10 kD membrane

Materials of construction

Membrane	Polyethersulfone
Screen	Polypropylene
Encapsulent and gasket	Silicone
Wetting solution	0.1-0.2 N NaOH and 20-22% glycerin

Table 4. Kvick Flow cassettes

Code number	Catalog number	Membrane area (m^2)	Membrane area (ft^2)	Rating (NMWC*)	Holdup volume (ml)
56-4113-49	UFEFL 0005 050 ST	0.46	5	5 kD	30
56-4113-47	UFEFL 0010 050 SE	0.46	5	10 kD Select**	30
56-4113-50	UFEFL 0010 050 ST	0.46	5	10 kD	30
56-4113-51	UFEFL 0030 050 ST	0.46	5	30 kD	30
56-4113-52	UFEFL 0050 050 ST	0.46	5	50 kD	30
56-4113-54	UFEFL 0100 050 ST	0.46	5	100 kD	30
56-4113-37	UFEFL 0005 250 ST	2.33	25	5 kD	150
56-4113-38	UFEFL 0010 250 SE	2.33	25	10 kD Select**	150
56-4113-39	UFEFL 0010 250 ST	2.33	25	10 kD	150
56-4113-40	UFEFL 0030 250 ST	2.33	25	30 kD	150
56-4113-41	UFEFL 0050 250 ST	2.33	25	50 kD	150
56-4113-43	UFEFL 0100 250 ST	2.33	25	100 kD	150

* Nominal molecular weight cutoff
** 10 kD Select is a tighter 10 kD membrane

Materials of construction

Membrane	Polyethersulfone
Screen	Polypropylene
Encapsulent and gasket	Silicone
Wetting solution	0.1-0.2 N NaOH and 20-22% glycerin

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